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PATENT Docket No. 399632001920

CERTIFICATE OF MAILING BY "FIRST CLASS MAIL"

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Ruth M. Saskowski

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Alessandro Sette, et al.

Serial No.:

09/189,702

Filing Date:

10 November 1998

For:

HLA BINDING PEPTIDES AND

THEIR USES

Examiner: Ronald B. Schwadron, Ph.D.

Group Art Unit: 1644

DECLARATION OF SCOTT SOUTHWOOD

Assistant Commissioner for Patents Washington, D.C. 20231

Dear Sir:

I, Scott Southwood, declare as follows:

- I am a co-inventor in the above-referenced application and am an experienced immunochemist. A copy of my curriculum vitae is attached hereto as Exhibit A.
- 2. I, along with Elissa Keogh prepared the technical report attached hereto as Exhibit B in the course of my employment at Epimmune, Incorporated. This report provides the results of a number of experiments we conducted on epitopes which are HLA-A2.1 restricted. The methods to assess immunogenicity are similar to those set forth in various papers made of record herein published by our group. The most relevant of these methods is set forth on

pages 8-12 of the Report. Briefly, the .221A2.1 cell line, which is produced by transferring the HLA-A2.1 gene into a cell line that is null for MHC alleles was used as a target cell. Tumor cells which were typed for HLA-A2.1 were also used as targets. CTL's were generated from PBMC by contacting CD8⁺ cells with dendritic cells also prepared from PBMC and pulsed with the peptide to be tested. The CTL's generated by the mixture of dendritic cells loaded with peptide and CD8⁺ cells were then test for their ability to lyse targets as measured by ⁵¹Cr release.

- 3. The results for the CEA derived peptide YVCGIQNSV (SEQ. ID. NO: 31) are shown in Table 2 on page 31 of the report. As shown, CTL's could be generated with respect to the .221A2.1 cell line (second column from the right) although in this experiment no CTL's targeting the tumor targets were found.
- 4. The success of this peptide in stimulating a CTL response against the .221A2.1 cell line demonstrates that this peptide is immunogenic.

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements are made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Executed at San Diego, California, on 18 January 2002.

Scott Southwood